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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,062	05/10/2002	A Satyanarayan Naidu	50046290-0007	9560

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,062	NAIDU, A SATYANARAYAN	
	Examin r	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on th cover she t with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49,51 and 56-203* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *14-17,40-47,51,59-61,63,66,67,69-85,91,93-98,100 and 118* is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☒ Claim(s) *See Continuation Sheet* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Continuation of Disposition of Claims: Claims rejected are 1-3,5,11,18-20,22,28,31,32,38,39,86-90,92,101-104,106,115-117,119-124,126-129,131-138,142-151,153,154,157-159,162-165,171-173,175,176,179-181,184-187,193-197 and 200-203.
Continuation of Disposition of Claims: Claims objected to are 4,6-10,12,13,21,23-27,29,30,33-37,48,49,56-58,62,64,65,68,99,105,107-114,125,130,139-141,152,155,156,160,161,166-170,174,177,178,182,183,188-192,198 and 199.

1. The amendment to the specification, second paragraph after the heading "Detailed Description of the Preferred Embodiments", contained in the response filed November 3, 2003 has not been entered because the marked-up amended paragraph does not correspond to the paragraph being replaced. The specification paragraph (at page 10, lines 1-8) discusses sources of the LF peptide, whereas the amendment paragraph discusses substrates for immobilization of the LF. It appears that the amendment instruction gives the wrong location for the paragraph to be replaced. Also, the amendment instruction should use page and line numbers of the specification to identify the paragraph to be amended, rather than just counting the number of paragraphs following a heading.

In the amendment filed November 3, 2003, in claim 6, the deleted word "immibolized" was not marked with brackets as required by 37 CFR 1.121. At claim 48, line 2, "species" was changed to "sp" without appropriate marking. In claim 70, the status of the claim is inconsistent with the underlining which is present in the claim. In claim 93, the phrase "isolated lactoferrin immobilized on a naturally occurring substrate via the N-terminus region of the" has been inserted without marking. In claim 99, "a jar" has been re-written as "ajar" without marking. In claim 120, "formulated" has been changed to "119" without marking. In claim 155, the deleted semicolon was not marked with brackets. In any future amendments, the amendments should be carefully reviewed to ensure full and accurate compliance with the amendment rules.

2. The claim for priority inserted at page 1, lines 5-6, of the specification by the preliminary amendment filed November 28, 2001 is objected to because it is not the first sentence of the specification. Further, the claim for priority is objected to because it does not use appropriate language for claiming the benefit of a PCT application under 35 U.S.C. 371 and because it does

not use appropriate language for claiming the benefit of a non-provisional application (e.g., continuation, divisional, continuation-in-part). See MPEP 201.11 (III).

The amendment submitted November 3, 2003 uses the same improper priority claim language as did the amendment filed November 8, 2001. Further, Applicants' response did not include any instruction deleting the claim for priority inserted by the preliminary amendment filed November 28, 2001.

Correction is required.

3. Claims 20, 86-90, 92, 104, and 120-122 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claim 20 recites that the naturally occurring substrate can be collagen, and thus contradicts the independent claim where this possibility is explicitly excluded. Claim 104 is indefinite for the same reason. There is no antecedent basis in the claims for the phrase "the composition" at claim 86, line 2. Note that at line 1 of the claim, "composition" was changed to "foodstuff". Claim 120 is dependent upon claim 122, which is dependent upon claim 120. Therefore, neither claim 120 nor 122 (nor claim 121 for analogous reasons) are ultimately dependent upon an independent claim. It is believed that claim 120 should instead depend upon claim 119.

4. Claims 48, 99, and 120 are objected to because of the following informalities: At claim 48, line 2, "sp" should be changed back to "species". At claim 99, line 4, "ajar" should be changed back to "a jar". At claim 120, line 2, "119" should be changed back to "formulated". Appropriate correction is required.

5. Claims 20, 104, and 120 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 20 and 104 embrace a naturally occurring substrate which is gelatin, and thus are broader in scope than independent claims 18 and 102, respectively, where the naturally occurring substrate is defined as not including gelatin. Claim 120 does not further limit a previous claim; rather, claim 120 is dependent upon subsequent claim 122.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 20 and 104 are rejected under 35 U.S.C. 102(b) as being anticipated by the Russian Patent 2,099,065. The Russian Patent '065 teaches a gel comprising lactoferrin, gelatin, and Na phosphate buffer. A gel is a colloid. The gel is administered to the oropharyngeal zone of a patient being given chemo-radiation therapy for tumors. Because the same components are present in the same defined dispersion, inherently the lactoferrin in the gel of Russian Patent '065 will be immobilized via its N-terminus to the gelatin to the same extent claimed by Applicant. Because the same composition is being administered to the same patient by the same method steps, inherently microbial contamination of the oropharyngeal zone will be reduced in the method of the Russian Patent '065 to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the composition of the Russian Patent '065 and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than the composition of the Russian Patent

'065. With respect to instant claim 102, the liquid (which will be water) present in the gel of the Russian Patent '065, and the gelatin present in the gel of the Russian Patent '065, correspond to Applicant's pharmaceutically acceptable carrier. With respect to instant claim 104, an intended use limitation does not impart novelty or nonobviousness to a composition claim which is otherwise anticipated by or obvious over the prior art.

8. Claims 1, 2, 11, 18, 19, 28, 31, 38, 39, 101-103, 119-124, 126-129, 131, 132, 134, 142-148, 197, 200, and 203 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 91/13982. The WO Patent Application '982 teaches lactoferrin in combination with stearic acid (which is a lipid and also corresponds to Applicant's pharmaceutically acceptable carrier of claim 102) or its salts. The composition is used as an antiseptic. Lactoferrin concentrations on the surfaces to be treated are 0.1-1 mg/6 cm^2 (approximately equal to 0.1-1 mg/in^2). Buffers can be present in the antiseptic compositions of the reference. See, e.g., page 7, line 30 - page 9, line 24. Because the same components are present in the same defined dispersion, inherently the lactoferrin in the composition of the WO Patent Application '982 will be immobilized via its N-terminus to the stearic acid to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the composition of the WO Patent Application '982 and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than the composition of the WO Patent Application '982. With respect to instant claims 101, 122-124, 126-129, 131, 132, 134, and 142-148, note that an intended use limitation does not impart patentability to composition claims where the composition is otherwise anticipated by or

obvious over the prior art, and that these claims do not structurally or functionally limit the claimed compositions so as to distinguish over those taught by the WO Patent Application '982.

9. Claims 149-151, 153, 164, 171-173, 175, 186, and 193-195 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 91/13982. Application of the WO Patent Application '982 is the same as in the above rejection of claims 1, 2, 11, 18, 19, 28, 31, 38, 39, 101-103, 119-124, 126-129, 131, 132, 134, 142-148, 197, 200, and 203. The WO Patent Application '982 teaches administering its antiseptics to mammals, but does not particularly teach treating humans or non-human vertebrates. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to use the antiseptic compositions of the WO Patent Application '982 to treat both human and non-human mammals because it is desirable to treat both human and non-human mammals with antiseptics and because the activity of the antiseptic compositions of the WO Patent Application '982 would not have been expected to be affected by the subject being treated, but rather would have been expected to have general utility regardless of where the source of microbial contamination is found.

10. Claims 1, 2, 5, 18, 19, 22, 31, 101-103, 106, 115-117, 119-124, 126-129, 131-132, 134, 136, 142-151, 153, 164, 171-173, 175, 186, 193-197, and 200-203 are rejected under 35 U.S.C. 102(b) as being anticipated by the European Patent Application 753,309. The European Patent Application '309 teaches compositions comprising lactoferrin and carriers such as paraffin oil and Vaseline (which are lipids), xantan gum and corn starch (which are polysaccharides), and lecithin (which is an emulsifier). The compositions are in the form of ointments, creams, gels, and powders The compositions are used to prevent or treat viral infections on the skin or mucosae of humans or animals. See, e.g., the Abstract; Examples 5-8; and claim 1. Because the

same components are present in the same defined dispersion, inherently the lactoferrin in the composition of the European Patent Application '309 will be immobilized via its N-terminus to the paraffin oil, Vaseline, xantan gum, and corn starch to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the composition of the European Patent Application '309 and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than the composition of the European Patent Application '309. With respect to instant claim 101, an intended use limitation does not impart patentability to product claims which are otherwise anticipated by or obvious over the prior art.

11. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being obvious over the European Patent Application 753,309. Application of the European Patent Application '309 is the same as in the above rejection of claims 1, 2, 5, 18, 19, 22, 31, 101-103, 106, 115-117, 119-124, 126-129, 131-132, 134, 136, 142-151, 153, 164, 171-173, 175, 186, 193-197, and 200-203. The European Patent Application '309 does not teach a lactoferrin/surface area ratio for the surfaces to be treated. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal doses for the lactoferrin-containing compositions of the European Patent Application '309 because dose is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

12. Claims 1, 2, 5, 18, 19, 22, 31, 32, 101-103, 106, 115, 119-124, 126-129, 131-136, 142-151, 153, 159, 162-165, 171-173, 175, 181, 184-187, 193-197, and 200-203 are rejected under 35 U.S.C. 102(b) as being anticipated by the European Patent Application 753,308. The

European Patent Application '308 teaches compositions comprising lactoferrin and peppermint oil, gum base and corn starch (which are polysaccharides), glucose, and additional antibiotic compounds such as erytromicin and ampicillin. The compositions are in the form of gargles, aqueous solutions, chewing gum, and powders The compositions are used to prevent or treat bacterial infections such as by S. aureus and S. pyogenes on the skin or mucosae of humans or animals. See, e.g., the Abstract; Examples 5-8; and the claims. Because the same components are present in the same defined dispersion, inherently the lactoferrin in the composition of the European Patent Application '308 will be immobilized via its N-terminus to the peppermint oil, gum base, and corn starch to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the composition of the European Patent Application '308 and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than the composition of the European Patent Application '308. With respect to instant claim 101, an intended use limitation does not impart patentability to product claims which are otherwise anticipated by or obvious over the prior art.

13. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being obvious over the European Patent Application 753,308. Application of the European Patent Application '308 is the same as in the above rejection of claims 1, 2, 5, 18, 19, 22, 31, 32, 101-103, 106, 115, 119-124, 126-129, 131-136, 142-151, 153, 159, 162-165, 171-173, 175, 181, 184-187, 193-197, and 200-203. The European Patent Application '308 does not teach a lactoferrin/surface area ratio for the surfaces to be treated. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal doses for the

lactoferrin-containing compositions of the European Patent Application '308 because dose is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

14. Claims 1-3, 5, 18-20, 22, 31, 32, 102-104, 106, 115, 119, 124, 137, 138, 142-150, 154, 164, 165, and 203 are rejected under 35 U.S.C. 102(e) as being anticipated by Kruzel et al (U.S. Patent No. 6,066,469). Kruzel et al teach nutritional supplements comprising lactoferrin in combination with adjuvants or diluents such as cellulose, starch, gelatin, tragacanth, and sodium carboxymethylcellulose. Lactoferrin acts to treat or prevent bacterial, viral, and fungal infections, such as S. pneumoniae infections. See, e.g., column 6, lines 40-56, and column 8, line 47 - column 9, line 7. Because the same components are present in the same defined dispersion, inherently the lactoferrin in the nutritional supplements of Kruzel et al will be immobilized via its N-terminus to the carriers or diluents to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the compositions of Kruzel et al and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than the compositions of Kruzel et al. With respect to instant claims 144-148, an intended use does not impart patentability to composition claims where the composition is otherwise anticipated by or obvious over the prior art.

15. Claim 203 is rejected under 35 U.S.C. 102(b) as being anticipated by the Harper et al text in view of Okonogi et al (U.S. Patent No. 4,791,193). The instant claims are inherently anticipated by milk and the drinking of milk. The Harper et al text teaches that milk inherently comprises casein, triglycerides, lactose (a disaccharide comprising galactose), α-lactalbumin,

IgA, lysozyme, and nucleic acids in an aqueous solution. The Harper et al text also teaches that milk inherently comprises citrate, phosphate, and carbonate buffer salts. Okonogi et al teach that lactoferrin is inherently present in milk (see column 1, lines 11-25). Because the same components are present in the same aqueous solution, inherently the lactoferrin in milk will be immobilized on the casein, triglycerides, lactose, α-lactalbumin, IgA, lysozyme, and nucleic acids which are inherently present in milk to the same extent claimed by Applicant. Sufficient evidence of similarity between the milk of the Harper et al text and Applicant's claimed composition is deemed to be present to shift the burden to Applicant to demonstrate that the claimed composition is unobviously different than that of milk. The drinking of milk brings the immobilized lactoferrin into contact with the mouth and oral cavity, which is inherently subject to microbial contamination. Because the same immobilized lactoferrin-containing composition is being applied to the same composition subject to microbial contamination, inherently microbial contamination will be reduced to the same extent claimed by Applicant. Note that the rejected claims do not require lactoferrin to be present in isolated form. With respect to instant claims 98-100, these claims are inherently anticipated by milk which occurs in cartons, bowls, cups, and bottles. With respect to instant claim 101, an intended use does not impart patentability to composition claims where the composition is otherwise anticipated by or obvious over the prior art.

16. Claim 203 is rejected under 35 U.S.C. 102(b) as being anticipated by the Harper et al text in view of Okonogi et al as applied against claim 203 above, and further in view of the Naidu et al article (Env. Nutr. Interactions, Vol. 2, pages 35-50). The Naidu et al article teaches that lactoferrin complexes with casein, α-lactalbumin, lysozyme, and IgA (see page 45, first full

paragraph), and thus is further evidence that the milk of the Harper et al text inherently comprises immobilized lactoferrin. The Naidu et al article teaches that lactoferrin blocks the growth of B. subtilis, E. coli, S. dysentriae, and C. albicans (see the paragraph bridging pages 38 and 39), and thus is further evidence that drinking the milk of the Harper et al text inherently will reduce microbial contamination by these microbes.

17. Claims 102-104, 115-117, 119, 124, 127, 128, 137, 138, 142-148, 154, 157, 158, 171, 172, 176, 179, 180, 186, and 193-196 are rejected under 35 U.S.C. 102(e) as being anticipated by Gohlke et al (U.S. Patent No. 6,475,511). Gohlke et al teach lactoferrin combined with colostrum (which inherently contains proteins such as casein, polysaccharides, lipids, lactose, cholesterol, physiological emulsifiers, monoglycerides, and diglycerides), pectin (which is a polysaccharide), and pharmaceutically acceptable carriers such as dextrose (see, e.g., Examples 1-3). The components are thoroughly mixed and cold pressed to form a lozenge. The lozenges are administered to the oral mucosa, whereby the lactoferrin is absorbed and enters the bloodstream and inhibits infections in mammals, especially humans (see, e.g., the abstract). Because the same components are present in the same compositions, inherently the lactoferrin in the lozenges of Gohlke et al will be immobilized via its N-terminus to the proteins, polysaccharides, and lipids which are present to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the compositions of Gohlke et al and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than the compositions of Gohlke et al. With respect to instant claims 142-148, an intended use does not impart patentability to composition claims where the composition is otherwise anticipated by or obvious over the prior art.

Gohlke et al is available as prior art against instant claims 102-104, 115-117, 119, 124, 127, 128, 137, 138, 142-148, 154, 157, 158, 171, 172, 176, 179, 180, 186, and 193-196 because these claims are not entitled under 35 U.S.C. 120 to the benefit of the filing date of grandparent application 09/322,700. These claims are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of the grandparent application '700 because the grandparent application '700, under the test of 35 U.S.C. 112, first paragraph, does not disclose pharmaceutically acceptable carriers, does not disclose systemic administration, does not disclose administration through a transmucosal delivery route, does not disclose ingestive delivery systems such as lozenges, and does not disclose administering to non-human vertebrates in general.

For other claims whose subject matter may be taught or suggested by Gohlke et al, i.e. claims 1-3 and 18, these other claims are deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of grandparent application 09/322,700. The subject matter of Gohlke et al, and especially that subject matter relied upon in the above rejection, is not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/096,697, and therefore Gohlke et al is not available as prior art against these other claims.

18. Applicant's arguments filed November 3, 2003 have been fully considered but they are not persuasive.

The terminal disclaimer filed November 3, 2003 has been approved and overcomes the obviousness-type double patenting rejection set forth in the previous Office action.

The Russian Patent 2,099,065 remains applied against instant claims 20 and 104, which recite that the naturally occurring substrate can be gelatin.

The rejections based upon the WO Patent Application 91/13982 as the primary reference are maintained. Applicant argues that lactoferrin is not capable of biding to stearic acid via the N-terminus region of the lactoferrin. Applicant also argues that special conditions are required in order to get lactoferrin to bind a substrate via the N-terminus region of the lactoferrin. However, Applicant has not submitted any evidence to support these arguments. Stearic acid is a species of one of the claimed naturally occurring substrates, i.e. is a lipid. Applicant's specification at page 11, line 1 ("any suitable technique") indicates that no special conditions are required for lactoferrin to bind to a substrate via its N-terminus region. The use of deionized water is only exemplary. Accordingly, sufficient evidence is present to establish prima facie anticipation. The prima facie case is not rebutted by attorney's arguments in the absence of experimental evidence that shows that lactoferrin does not bind to stearic acid via the N-terminus region of the lactoferrin. Applicant also has not offered any explanation as to why the positively charged N-terminus region of lactoferrin would not immobilize on the negatively charged carboxylic acid groups of the stearic acid/substrate. Finally, Applicant argues that if the lactoferrin is not immobilized by its N-terminus region, its antimicrobial activity will be adversely affected (see page 33, third paragraph, of the response). Because the lactoferrin of the WO Patent Application '982 retains its antiseptic properties even after combination with the stearic acid, the implication is that the lactoferrin must have been immobilized to the stearic acid by its N-terminus region.

The rejections based upon the European Patent Application 753,309 are maintained for the same rationale given in the above paragraph. Applicant claims polysaccharides and lipids in general as substrates, and the paraffin oil, Vaseline, xantan gum and corn starch of the European

Patent Application '309 are species of the claimed polysaccharides and lipids. This is sufficient for prima facie anticipation. With respect to the possibility that the emulsifier of the European Patent Application '309 may bind to regions in addition to the N-terminal region of lactoferrin, this is permitted by Applicant's claims. Applicant's claims contain no language which require the lactoferrin to be immobilized to the substrate only by its N-terminus region and not by another region. Independent claim 1 does not even require that the immobilized lactoferrin exhibit antimicrobial activity. Patentability must be based upon claimed, not unclaimed, differences over the prior art.

The rejections based upon the European Patent Application 753,308 and Kruzel et al (U.S. Patent No. 6,066,469) are maintained for reasons analogous to those given above.

Claim 203 is rejected over the Harper et al text in view of Okonogi et al, optionally in combination with the Naidu et al article (Env. Nutr. Interactions, Vol. 2, pages 35-50). Claim 203 does not require its lactoferrin to be isolated.

Braun et al (U.S. Patent Application Publication 2003,0229011) is cited as art of interest. For those of Applicant's claims where Braun et al teaches or suggests the claimed subject matter (e.g., claims 1-3), Braun et al is not prior art against these claims because these claims are entitled under 35 U.S.C. 120 to the benefit of the filing date of grandparent application 09/322,700. Note with respect to instant claim 85, which requires three components to be present, i.e. the foodstuff, the isolated lactoferrin, and the naturally occurring substrate, Braun et al do not teach or suggest the naturally occurring substrate.

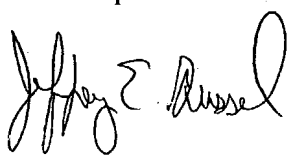
19. Claims 14-17, 40-47, 51, 59-61, 63, 66, 67, 69-85, 91, 93-98, 100, and 118 are allowed. Claims 4, 6-10, 12, 13, 21, 23-27, 29, 30, 33-37, 49, 56-58, 62, 64, 65, 68, 105, 107-114, 125,

130, 139-141, 152, 155, 156, 160, 161, 166-170, 174, 177, 178, 182, 183, 188-192, 198, and 199 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 48 and 99 would be allowable if rewritten or amended to overcome the claim objections set forth in this Office action. Claims 86-90 and 92 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

PLEASE NOTE: Sometime on or around January 6, 2004, the examiner will be moving to the new USPTO headquarters. At that time, the examiner's phone number will change to (571) 272-0969. After January 6, it is recommended that Applicants attempt to contact the examiner at the new phone number if they are unable to reach him using the old number.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Technology Center 1600 for formal communications is (703) 872-9306; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1600 receptionist is (703) 308-0196.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
January 7, 2004